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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,468	04/12/2004	Sanford D. Altman	OAV-103XC1	4577

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO Box 142950
GAINESVILLE, FL 32614

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
06/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,468	ALTMAN, SANFORD D.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,11-16,24-28 and 31-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,11-16,24-28 and 31-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 April 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

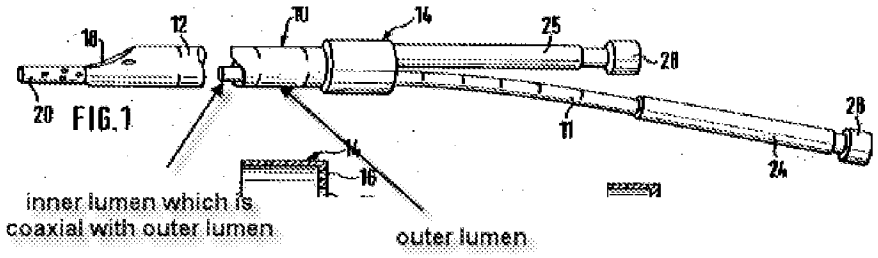
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3-7, 11-16, 24, 25, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Us 4,385,631 to Uthmann.

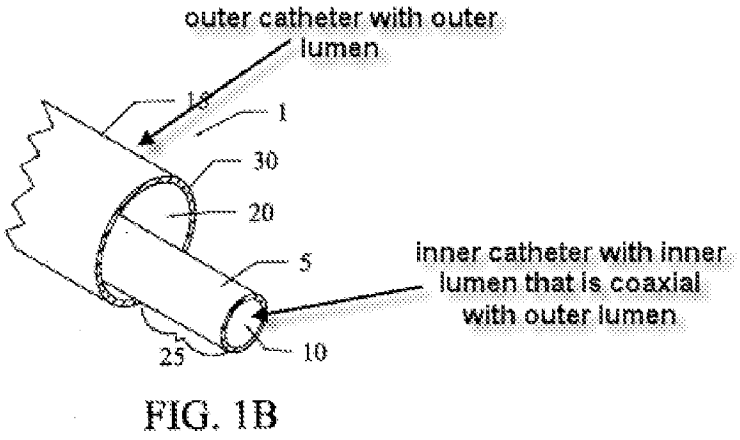
In the specification and figures, Uthmann discloses the apparatus substantially as claimed by Applicant.

With regard to claim 1, Uthmann discloses a dual-lumen catheter with a first arterial, interior catheter 11 with distal end 20, a second, venous, outer catheter 12, both of which are attached to a hollow hub or cap 14 (see FIG 1 and accompanying text). The two lumens are coaxial along their entire length to hub or cap 14. (Applicant

illustrates that FIGS 1A and1B of the instant specification illustrate a coaxial configuration. In FIG 1B, the inner catheter is offset from the center of the outer catheter. Since the catheters still share some of the same axis, this configuration is interpreted by the Examiner to encompass the coaxial configuration claimed by Applicant. Furthermore, Applicant illustrates that the lumens are coaxial to the hub 40 in FIG 2B. Accordingly, it is the position of the Examiner that the lumens disclosed by Uthmann are coaxial along the entire length as illustrated by Applicant.) The arterial lumen's distal tip 20 may extend beyond the distal end of venous catheter 12 (see FIG 1). Both lumens are slideable within the cap 14 and may be removed without altering the structure of either tube (see column 2, lines 48-67). Uthmann discloses that both the venous and arterial lumens have a plurality of distal openings. However, it has been held that the omission of an element (such as an opening) and its function is obvious if the function of the removed element is not desired. See MPEP § 2144.04(II)(A). Since Applicant does not desire the function of multiple holes, it would have been obvious to one having ordinary skill in the art at the time of invention to eliminate the undesired holes from the apparatus disclosed by the cited prior art.



1: Uthmann FIG 1, annotated by Examiner



2: Applicant's FIG 1B, annotated by Examiner

With regard to claims 3-5 and 12-14, Uthmann is silent as to the distance between the distal end of the inner lumen and the distal end of the outer lumen. However, Uthmann clearly discloses that the inner lumen 11 is slideable within the outer

lumen 12 (see column 1, lines 58-67). As such, Uthmann discloses that the disclosed catheter is capable of being deployed with variable distances between the inner and outer tips. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP § 2144.05 (II)(A). In the instant case, Uthmann discloses that the distance between the tips may be adjusted to minimize pendulum blood flow (see column 1, lines 40-55). By varying the distance between the distal ends, a change in pendulum blood flow results. Accordingly, it is the position of the Examiner that the distance between the distal ends, which is adjustable, as taught by Uthmann, is a result-effective variable, the optimization of which is not patentable over the cited prior art.

With regard to claims 6, 7, 15, 16 Uthmann discloses that the distal end of the venous or outer lumen is tapered at 18 and the tip of the arterial or inner catheter 11 comprises a conical, or tapered tip (see FIGS 1, 2, column 2, lines 64-68).

With regard to claim 11, Uthmann illustrates that the inner catheter 11 lays against the wall of outer catheter 12, creating a circle-c configuration (see FIG 1).

With regard to claims 24 and 25, Uthmann illustrates that the venous or outer lumen comprises at least two apertures 19, which are illustrated as having an oval shape.

With regard to claims 31 and 33, Uthmann disclose that an incision is made into a blood vessel, the claimed catheter is inserted into the patient over a guidewire or guidance spiral, and blood is withdrawn, treated, and returned (see column 3, line 389 to column 4, line 11).

4. Claims 27, 28, 32, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,385,631 to Uthmann in view of US 6,758,836 to Zawacki.

In the specification and figures, Uthmann suggests the apparatus and method substantially as claimed by Applicant (see rejection above).

With regard to claim 27, Uthmann fails to disclose that the catheter is constructed of the claimed materials. Zawacki discloses a split tip dialysis catheter with slideable lumens wherein the catheter may be made of thermoplastics such as PTFE (see column 3, lines 24-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use thermoplastics such as PTFE in the catheter disclosed by Sorenson, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claim 28, Uthmann fails to disclose that the catheter comprises the claimed reinforcing materials. Zawacki discloses that reinforcing substances to reduce kinking may be used in the construction of the catheter, including wire (which is a metal formed as a flexible thread), which meets applicant's claim drawn to a metal (see column 4, lines 34-38). Therefore, it would have been obvious to add metal as disclosed by Zawacki to the catheter disclosed by Uthmann in order to reinforce the catheter structure, as taught by Zawacki.

With regard to claim 32, Uthmann suggests the method substantially as claimed by Applicant with the exception of deploying the catheter in the claimed location.

However, Zawacki specifically discloses that the catheter may be introduced so that the catheter lies at the junction of the superior vena cava and the right atrium and that the position of the inner and outer lumens may be adjusted to provide for the correct location of the lumens within the vasculature (see column 3, lines 7-67). Therefore, it would have been obvious to place the lumens of the catheter disclosed by Zawacki in the locations claimed by applicant, since Zawacki suggests such positioning and teaches that the catheter is adjustable.

With regard to claim 34, Uthmann discloses a hub, but does not specifically teach that the catheters are replaceable. Zawacki discloses that the catheter assembly 10 comprises a hollow hub 40 that connects to the assembly (see FIG 1, column 3, lines 48-67). Zawacki further discloses that the inner lumen—which may act as either the venous lumen or arterial lumen, depending on the operation of the catheter (see column 4, lines 5-18)—is removable and replaceable (see column 1, lines 61-67).

With regard to claim 35, Uthmann fails to disclose the exact location of the insertion point. Zawacki discloses that the catheter may be inserted into one of the large central veins, which may include a jugular or subclavian vein (see column 2 line 65 to column 3, line 22).

5. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,385,631 to Uthmann in view of US 6,595,966 to Davey et al.

In the specification and figures, Uthmann suggests the device substantially as claimed by applicant (see rejection above) with the exception of a therapeutic agent.

With regard to claim 26, Davey discloses that a surface of the conduit may be treated with heparin, an anticoagulant, in order to prohibit deposit of materials on the surface of the conduit (see column 2, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter suggested by the prior art with a therapeutic agent such as an anticoagulant as disclosed by Davey in order to prevent deposit of materials on the surface of the conduit, as taught by Davey.

Response to Arguments

6. Applicant's arguments filed 15 April 2009 have been fully considered but they are not persuasive.

7. Applicant argues that Uthmann teaches that the two catheters of the disclosed invention are not coaxial in nature. However, Uthmann teaches that outer catheter 12 forms the longitudinal guide, or sliding surface, for inner catheter 11. Uthmann further illustrates the sliding of the inner and outer catheters relative to one another. Applicant notes that Uthmann discloses that the lumens are “axially separated" (Claim 1). However, the Examiner notes that this axial separation is claimed as being at the “other end” from the blood insertion end. Accordingly, it is the position of the Examiner that the Uthmann catheters are coaxial from the insertion point to the hub.

8. Applicant further argues that the position of the withdrawal and return catheters in Uthmann is reversed from that claimed by Applicant. However, it is the position of the Examiner that Applicant’s recitation of “arterial” and “venous” lumens are a statement of

the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, either lumen of the Uthmann devices is capable of withdrawing or returning blood from and to the patient, thereby meeting the limitations of the claims. Since the names of the lumens do not connote any particular structure, Uthmann does not teach away from the claimed invention.

9. Applicant argues that Zawacki teaches two, distinct, separate, non-coaxially situated catheter tips. The Examiner respectfully disagrees. Applicant discloses that FIG 1B of the instant drawing comprises a coaxial configuration, in which the inner catheter is situated eccentric to the outer catheter. The Zawacki catheters, as shown in FIGS 1-6, comprise the same general configuration, in which inner catheter 30 sits inside and eccentric to outer catheter 20. Accordingly, it is the position of the Examiner that the cited prior art suggests a coaxial catheter arrangement that fits the description provided by Applicant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
11 June 2009